50-26-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Appointment of Administrative Dispute Resolution Board Members

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: On December 14, 2020, the Department of Health and Human Services published in the Federal Register a final rule ("Rule") establishing the 340B Drug Pricing Program (340B Program) Administrative Dispute Resolution (ADR) Board (hereafter, "the Board"). See 85 FR 80632 (Dec. 14, 2020). According to the Rule, the purpose of the 340B Program's ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the Public Health Service Act, that a covered entity has violated the prohibitions on diversion or duplicate discounts. The Rule states that Board members from the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) must have relevant expertise and experience in drug pricing or drug distribution. The Rule also states that Board members from the Office of the General Counsel (OGC) must have expertise and experience in handling complex litigation. From the 340B ADR Board, the HRSA Administrator will select three voting members, one from each of the three HHS operating/staff divisions involved (i.e., CMS, HRSA, OGC) to form 340B ADR Panels that will review claims and, pursuant to delegated authority from the Secretary, make certain final agency decisions.

All previous appointments to the Board are revoked. Based on recommendations from OGC, CMS, and HRSA, I hereby appoint the following Board members, who shall serve a term of two years, to be extended for additional terms upon agreement by the member and the head of his or her operating/staff division.

Sean R. Keveney, Deputy General Counsel, the Office of the General Counsel, Department of

Health and Human Services;

Andy J. Miller, National Complex Litigation and Investigations Division Attorney, the Office of

the General Counsel, Department of Health and Human Services;

Glenn Clark, Public Health Advisor, HIV/AIDS Bureau, Health Resources and Services

Administration, Department of Health and Human Services;

CAPT Christina Meade, Area Regional Pharmacy Consultant, Office of Regional Operations,

Health Resources and Services Administration, Department of Health and Human Services;

CDR Timothy Lape, Division of Medicare Health Plans Operations, Medicare Branch, Centers

for Medicare & Medicaid Services, Department of Health and Human Services;

Adele Pietrantoni Office of Program Operations and Local Engagement, Division of Drug and

Health Plan Operations, Centers for Medicare & Medicaid Services, Department of Health and

Human Services;

Chantelle Britton, Senior Advisor, Office of Pharmacy Affairs, Health Resources and Services

Administration, Department of Health and Human Services, as ex-officio, non-voting member;

and

Julie Zadecky, Pharmacist, Office of Pharmacy Affairs, Health Resources and Services

Administration, Department of Health and Human Services, as ex-officio, non-voting member.

Dated: June 21, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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